

REMARKS/ARGUMENTS

Claims 1, 4 and 23 are canceled. Claim 3 is amended and is now an independent claim. Claim 5 is amended to change the dependency from claim 4 to claim 3. New claim 27 is added with the amendment. Support for new claim 27 can be found in paragraphs [0024] to [0030] of the specification. Claims 2, 3, 5-19 and 27 are pending in this application. Claims 20-22 and 24-26 are presently withdrawn without prejudice.

Claim Rejections – 35 USC § 112

Claims 3-5 and 11-18 were rejected under 35 U.S.C. 112, first paragraph. Claims 3 and 4 have been combined with this amendment and the phrase “negative ion residue” no longer appears in these claims. Applicants respectfully submit that the 35 U.S.C. 112 rejection is no longer relevant to claim 3 as presently amended nor to the claims dependent on claim 3.

Claim Rejections – 35 USC § 102

1. Rejection of claims 1-2 and 6, 8-10 under 35 U.S.C. §102(b) as being anticipated by WO 9941298 (WO'298; US 6685966 is English equivalent: '966)

The Examiner characterizes WO'298 as disclosing drug-containing nanoparticles provided by causing primary nanoparticles containing a hydrophobic active material (fat-soluble drug) to act with alkali earth metal salts (bivalent metal salts) to give secondary nanoparticles, and causing bases such as sodium hydroxide or potassium hydroxide (a monovalent basic salt) to act with the secondary particles.

However, applicants respectfully note that the composite particles of '966 are comprise at least --

one core including at least one organic polymer in which is dispersed at least one hydrophobic active material,

one external coating comprising at least one oxide and/or hydroxide of aluminum, of silicon, of zirconium and/or of a transition metal, and

one intermediate layer, present at least partially between the core and the external coating and comprising at least one alkali earth metal hydroxide.

(See the abstract of the '966 patent.) The organic polymer is preferably latex (col. 2, lines 13-14) and can be cross-linked (col. 2, line lines 31-35). Some examples of suitable polymers include polystyrenes, copolymers of styrene with acrylates or butadiene, methacrylate, acrylamide among the many examples listed in column 2 of the '966 patent.

In contrast, the nanoparticles of the present invention are not the composite particles as disclosed in the '966 patent and an organic polymer is not used for preparing the nanoparticles of the present invention. The invention of present application is neither "patented nor described" in the '966 patent and is therefore not anticipated by WO 9941298.

2. Rejection of claims 1, 3 and 11-18 under 35 U. S. C. §102(b) as being anticipated by WO 03033592 (WO'592)

The WO' 592 reference relates to a polymeric micelle composition comprising an amphiphilic block copolymer composed of a hydrophilic block and a hydrophobic block. There are no block polymers in the nanoparticles of the present invention and consequently the WO' 592 does not anticipate the invention of the present application.

Claim Rejections – 35 USC § 103

1. *Rejection of claims 4-5 under 35 U.S.C. §103(a) as being unpatentable over WO 03033592 (WO'592) in view of US 3701745 ('745)*
2. *Rejection of claim 6 under 35 U.S.C. §103(a) as being unpatentable over WO 9941298 (WO'298; US 6685966 is English equivalent: '966) in view of US 6159381 ('381)*
3. *Rejection of 19 is rejected under 35 U. S. C. §103(a) as being unpatentable over WO 9941298 (WO'298; US 6685966 is English equivalent: '966)*

As discussed above, the nanoparticles disclosed in WO 03033592 or WO 9941298 are significantly different from the nanoparticles as described in the present application.

Further, the invention disclosed in US 3701745 relates to a coating composition comprising a copolymer of vinylidene chloride. The coating dispersions of this patent are used to coat plastic film and paper (cellulosic) products. Someone seeking to create a pharmaceutical delivery composition is unlikely to look at a coating for plastic film and paper products for inspiration. The compositions from the coating arts may not safe nor pharmaceutical acceptable for a drug delivery system. In addition, applicants respectfully submit that they do not see where column 3, line 59 states that oleic acid is useful in micelle chemistry.

Likewise, a pharmaceutical researcher is unlikely to look to the waster paper treatment art, which is the subject area of the US 6159381 ('381) patent. It is only through impermissible use of hindsight based on the disclosure in the present application to even find the '381 patent in the context of the present application.

Therefore, the person skilled in the art does not have the motivation to combine

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these documents to make the present nanoparticles and applicants respectfully request that these rejections be withdrawn.

CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.

Respectfully submitted,

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